

based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(f) The Administrator may modify any part of the criteria for exemption as specified in paragraphs (c) and (d) of this section upon evidence of diversion or attempted diversion. In doing so, the Administrator shall issue and publish a Notice of Proposed Rulemaking in the FEDERAL REGISTER. The Administrator shall permit any interested persons to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the FEDERAL REGISTER a final order.

[68 FR 23204, May 1, 2003, as amended at 69 FR 74971, Dec. 15, 2004]

§ 1310.13 Exemption of chemical mixtures; application.

(a) The Administrator may, by publication of a Final Rule in the FEDERAL REGISTER, exempt from the application of all or any part of the Act a chemical mixture consisting of two or more chemical components, at least one of which is not a List I or List II chemical, if:

(1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.

(b) Any manufacturer seeking an exemption for a chemical mixture, not exempt under § 1310.12, from the application of all or any part of the Act, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) An application for exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The date of the application;

(3) The exact trade name(s) of the applicant's chemical mixture and:

(i) If the applicant formulates or manufactures the chemical mixture for

other entities, the exact trade names of the chemical mixtures and the names of the entities for which the chemical mixtures were prepared; and

(ii) If a group of mixtures (*e.g.* formulations having identical function and containing the same listed chemical(s)), the information required in paragraph (c)(3)(i) of this section and a brief narrative of their use.

(4) (i) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non-listed chemicals); or

(ii) If a group of mixtures, the concentration range for the listed chemical and a listing of all non-listed chemicals with respective concentration ranges.

(5) (i) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals; and

(ii) If a group of mixtures, how the group's properties differ from the properties of the listed chemical.

(6) A statement that the applicant believes justifies an exemption for the chemical mixture or group of mixtures. The statement must explain how the chemical mixture(s) meets the exemption criteria set forth in paragraph (a) of this section.

(7) A statement that the applicant accepts the right of the Administrator to terminate exemption from regulation for the chemical mixture(s) granted exemption under this section.

(8) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.

(d) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

(e) Within 30 days after the receipt of an application for an exemption under this section, the Administrator will notify the applicant of acceptance or rejection of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to

paragraph (c) of this section or requested pursuant to paragraph (d) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the exemption is granted, the applicant shall be notified in writing and the Administrator shall issue, and publish in the FEDERAL REGISTER, an order on the application. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

(f) The Administrator may, at any time, terminate or modify an exemption for any product pursuant to paragraph (e) of this section. In terminating or modifying an exemption, the Administrator shall issue, and publish in the FEDERAL REGISTER, notification of the removal of an exempt product or group of exempt products for which evidence of diversion has been found. This order shall specify the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator may suspend

the effectiveness of the order until he has reconsidered the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(g) A manufacturer of an exempted chemical mixture shall notify DEA in writing, of any change in the quantitative or qualitative composition of a chemical mixture that has been granted an exemption by application. Changes include those greater than the range of concentration given in the application or that remove non-listed chemical(s) given in the application as part of the formulation. A new application will be required only if reformulation results in a new product having a different commercial application or can no longer be defined as part of a group of exempted chemicals. DEA must be notified of reformulation at least 30 days in advance of marketing the reformulated mixture. For a change in name or other designation, code, or any identifier, a written notification is required. DEA must be notified of any changes at least 60 days in advance of the effective date for the change.

(h) Each manufacturer seeking exemption must apply for such an exemption. A formulation granted exemption by publication in the FEDERAL REGISTER will not be exempted for all manufacturers.

(i) The following chemical mixtures, in the form and quantity listed in the application submitted (indicated as the “date”) are designated as exempt chemical mixtures for the purposes set forth in this section and are exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822, 823, 830, 957 and 958):

EXEMPT CHEMICAL MIXTURES

Manufacturer	Product name ¹	Form	Date
[Reserved]			

¹ Designate product line if a group.

Drug Enforcement Administration, Justice

§ 1310.15

[68 FR 23204, May 1, 2003]

§ 1310.14 Exemption of drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) Any manufacturer of a drug product containing ephedrine in combination with another active medicinal ingredient, the product formulation of which is not listed in the compendiums set forth in § 1310.01(b)(28)(i)(D)(I), may request that the Administrator exempt the product as one which contains ephedrine together with a therapeutically significant quantity of another active medicinal ingredient.

(b) An application for an exemption under this section shall contain the following information:

(1) The name and address of the applicant;

(2) The exact trade name of the drug product for which exemption is sought;

(3) The complete quantitative and qualitative composition of the drug product;

(4) A brief statement of the facts which the applicant believes justify the granting of an exemption under this section; and

(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Food, Drug, and Cosmetic Act.

(6) The identification of any information on the application which is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application which he deems necessary for determining if the application should be granted.

(d) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section

or requested pursuant to paragraph (c) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

[60 FR 32462, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822-3, 830, and 957-8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No exemption granted pursuant to 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in drug product compositions: Any change in the quantitative or qualitative composition of an exempt drug product listed in paragraph (d) requires a new application for exemption.

(d) In addition to the drug products listed in the compendium set forth in § 1310.01(b)(28)(i)(D)(I), the following